

Atty. Docket No. 0218.002.00003
U.S. Serial No. 10/762,533

REMARKS

Claims 1-38 are pending in this application.

Applicants wish to thank the Examiner for the courtesies extended during an in-person interview conducted on March 24, 2005. During the interview, a demonstration of the invention was presented to the Examiner. Applicants believe the Examiner recognized from the presentation that the invention is not described in the prior art.

Applicants also thank the Examiner for agreeing that the proposed amendment would overcome the rejections in the Final Office Action. The amendments presented here are substantially in accord with what was discussed with the Examiner during the interview by providing more of a context for the entire system claimed. Applicants believe these amendments serve a useful clarification purpose, and are desirable for clarification purposes, independent of patentability. Accordingly, Applicants respectfully submit that the claim amendments do not limit the range of any permissible equivalents.

In particular, claim 1 has been amended to more clearly show that the invention relates to a system of one or more rods disposed externally from the vertebrae by a plurality of fasteners such that the system permits movement of the first vertebra relative to the second vertebra. A slit integrally formed in a rod allows a portion of the rod to have a flexible element that permits movement between a first and second vertebra. As seen in several dependent claims, the system can be configured to provide targeted, limited movement in one direction, such as allowing some movement in the anterior-posterior direction, while substantially restricting movement in another direction, such as lateral bending and/or rotation.

As discussed during the interview, the amendment to claim 1 is fully supported by the specification. As no new matter has been added, Applicants respectfully request entry of these amendments at this time.

THE PROVISIONAL DOUBLE PATENTING REJECTION

The Examiner provisionally rejected the claims under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 1-59 of pending Application No. 10/443,755. Applicants will provide a terminal disclaimer to

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overcome this rejection upon confirmation by the Examiner that the pending claims are allowable.

THE CLAIM REJECTIONS BASED ON WU '618

The Examiner rejected claims 1-5, 22-29 and 32-38 as being anticipated by U.S. Patent No. 4,570,618 to Wu for the reasons provided on pages 3-4 of the Office Action. The Examiner then rejected claims 6-21 and 30-31 as obvious over Wu '618.

As discussed during the interview, Wu '618 does not teach or suggest several features recited in the claims. Wu '618 does not describe a spine stabilization system where a plurality of fasteners secure a stabilization rod externally to a first and second vertebra such that the system permits movement of the first vertebra relative to the second vertebra. Instead, Wu '618 teaches to place preformed wire members about the spine to stabilize the spine so that the vertebrae will remain in position, *i.e.*, not move. *See, e.g.*, Wu '618 at col. 1, lines 15-18. Furthermore, the ultimate objective of the structures of the Wu '618 patent is to achieve new bone growth between two vertebrae so that they are fused together. Wu '618 at col. 1, lines 5-34. This objective is achieved in part by packing the area around the wire(s) and longitudinally between the lamina with bone cement. *See, e.g.*, Wu '618 Figure 3, col. 2, lines 1-3.

In contrast, the provision of the flexible element integrally formed in the rod of the present invention allows a physician to install the spine stabilization system of the present invention in a manner similar to other external rod systems that are currently only capable of rigidly locking the vertebra in place relative to each other. Instead of rigidly locking the vertebrae in one position, however, the integrally formed flexible element in the rod allows relative movement of the vertebrae in one or more directions. In some instances, the movement is limited and can be directed to allow some movement in one direction while substantially restricting it in another. None of these features recited in the pending claims are described or suggested by Wu '618.

In fact, Wu '618 is not directed toward providing movement between a first and second vertebra. Instead, Wu teaches that the vertebrae will remain in a fixed position not only during healing of the bone fusion but also after healing. Wu '618 at col. 1, lines 15-18. Thus, Wu '618 teaches away from any suggestion to provide motion in one or more directions as presently claimed.

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Moreover, some of the dependent claims are particularly directed toward systems that provide limited movement in one direction while substantially restricting movement in another direction. *See, e.g.*, dependent claims 33 and 36. Other claims are directed toward particular configurations of the flexible element, or the direction in which two or more slits may travel. As discussed during the interview, there are a wide variety of advantages to these embodiments that simply can not be achieved with the structure disclosed in Wu '618.

For at least these reasons, applicants respectfully submit that, given the clarifying amendment included herein, the rejections based upon Wu '618 are now resolved and that the claims are in condition for allowance.

CONCLUSION

All claims are believed to be in condition for allowance. If the Examiner believes that the present amendments still do not resolve all of the issues regarding patentability of the pending claims, Applicants invite the Examiner to contact the undersigned attorneys to discuss any remaining issues. No fee is believed to be due for this submission. Should any fee be required, however, please charge such fee to CMFB PLLC Deposit Account No. 50-3120.

Respectfully submitted,

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By 

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